

LUPEROX® DTA

1. PRODUCT AND COMPANY IDENTIFICATION

Company

Arkema Inc.
900 First Avenue
King of Prussia, Pennsylvania 19406

Functional Additives

Customer Service Telephone Number: (800) 331-7654
(Monday through Friday, 8:00 AM to 5:00 PM EST)

Emergency Information

Transportation: CHEMTREC: (800) 424-9300
(24 hrs., 7 days a week)
Medical: Rocky Mountain Poison Center: (866) 767-5089
(24 hrs., 7 days a week)

Product Information

Product name: LUPEROX® DTA
Synonyms: Di-t-amyl peroxide
Molecular formula: C10 H22 O2
Chemical family: Organic peroxide - dialkyl peroxides
Molecular weight: 174.3 g/mol
Product use: Initiator

2. HAZARDS IDENTIFICATION

Emergency Overview

Color: colourless
Physical state: liquid
Odor: hydrocarbon-like

***Classification of the substance or mixture:**

Flammable liquid., Category 3, H226
Organic peroxides, Type E, H242
Skin Irritation, Category 2, H315
Skin sensitisation, Category 1, H317
Germ cell mutagenicity, Category 2, H341
Chronic aquatic toxicity, Category 4, H413

*For the full text of the H-Statements mentioned in this Section, see Section 16.

LUPEROX® DTA**GHS-Labeling**

Hazard pictograms:



Signal word:

Warning**Hazard statements:**

H226 : Flammable liquid and vapour.
H242 : Heating may cause a fire.
H315 : Causes skin irritation.
H317 : May cause an allergic skin reaction.
H341 : Suspected of causing genetic defects.
H413 : May cause long lasting harmful effects to aquatic life.

Supplemental Hazard Statements:

Organic peroxide.
Hazardous decomposition may occur.
Static accumulating flammable liquid. Can become electrostatically charged even in bonded and grounded equipment.
Sparks may ignite liquid and vapor.
May cause flash fire.

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Precautionary statements:
Prevention:

P201 : Obtain special instructions before use.
 P202 : Do not handle until all safety precautions have been read and understood.
 P210 : Keep away from heat/sparks/open flames/hot surfaces. No smoking.
 P220 : Keep/Store away from clothing/ combustible materials.
 P233 : Keep container tightly closed.
 P234 : Keep only in original container.
 P240 : Ground/bond container and receiving equipment.
 P241 : Use explosion-proof electrical/ ventilating/ lighting/ equipment.
 P242 : Use only non-sparking tools.
 P243 : Take precautionary measures against static discharge.
 P261 : Avoid breathing gas/mist/vapours/spray.
 P264 : Wash skin thoroughly after handling.
 P272 : Contaminated work clothing should not be allowed out of the workplace.
 P273 : Avoid release to the environment.
 P280 : Wear protective gloves/ eye protection/ face protection.
 P281 : Use personal protective equipment as required.

Response:

P303 + P361 + P353 : IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
 P308 + P313 : IF exposed or concerned: Get medical advice/ attention.
 P333 + P313 : If skin irritation or rash occurs: Get medical advice/ attention.
 P362 : Take off contaminated clothing and wash before reuse.
 P370 + P378 : In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

Storage:

P405 : Store locked up.
 P410 : Protect from sunlight.
 P411 + P235 : Maximum storage temperature is specified on label and in section 7 of SDS. Keep cool.
 P420 : Store away from other materials.

Disposal:

P501 : Dispose of contents/ container to an approved waste disposal plant.

3. COMPOSITION/INFORMATION ON INGREDIENTS
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Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Peroxide, bis(1,1-dimethylpropyl)	10508-09-5	>= 96 %	H226, H242, H315, H341, H413

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Hydroperoxide, 1,1-dimethylpropyl	3425-61-4	<= 1 %	H242, H226, H302, H311, H331, H314, H318, H317, H411
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****For the full text of the H-Statements mentioned in this Section, see Section 16.**

4. FIRST AID MEASURES

4.1. Description of necessary first-aid measures:

Inhalation:

If inhaled, remove victim to fresh air.

Skin:

In case of contact, immediately flush skin with soap and plenty of water. Get medical attention. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eyes:

Immediately flush eye(s) with plenty of water.

Ingestion:

If swallowed, DO NOT induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention.

4.2. Most important symptoms/effects, acute and delayed:

For most important symptoms and effects (acute and delayed), see Section 2 (Hazard Statements and Supplemental Information) and Section 11 (Toxicology Information) of this SDS.

4.3. Indication of immediate medical attention and special treatment needed, if necessary:

Unless otherwise noted in Notes to Physician, no specific treatment noted; treat symptomatically.

5. FIREFIGHTING MEASURES

Extinguishing media (suitable):

Water spray, Foam, Dry chemical

Extinguishing media (unsuitable):

Water may be ineffective., Do not use a solid water stream as it may scatter and spread fire.

Protective equipment:

Fire fighters and others who may be exposed to products of combustion should wear full fire fighting turn out gear (full Bunker Gear) and self-contained breathing apparatus (pressure demand / NIOSH approved or equivalent).

Further firefighting advice:

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Fight fire with large amounts of water from a safe distance.
Cool closed containers exposed to fire with water spray.
Closed containers of this material may explode when subjected to heat from surrounding fire.
After a fire, wait until the material has cooled to room temperature before initiating clean-up activities.
Do not allow run-off from fire fighting to enter drains or water courses.
Fire fighting equipment should be thoroughly decontaminated after use.

Fire and explosion hazards:

Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.

When burned, the following hazardous products of combustion can occur:

Carbon oxides

Hazardous organic compounds

Special Engineering Controls: To minimize static charge accumulation, flow rate should be restricted to less than 1 m/s (3 ft/s). When adding product to a hot reactor, closed system addition is recommended due to product volatility and flammability.

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, Emergency procedures, Methods and materials for containment/clean-up:**

Prevent further leakage or spillage if you can do so without risk. Evacuate area of all unnecessary personnel. Ventilate the area. Eliminate all ignition sources. Avoid generation of vapors. Contain and collect spillage with non-combustible absorbent material such as sodium bicarbonate, sodium carbonate, calcium carbonate, clean sand or non-acidic clay and then wet down (dampen) the mixture with water. DO NOT USE peat moss. Sweep or scoop up using non-sparking tools and place into suitable properly labeled containers for prompt disposal. The sweepings should be wetted down further with water. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits.

Protective equipment:

Appropriate personal protective equipment is set forth in Section 8.

LUPEROX® DTA**7. HANDLING AND STORAGE****Handling****General information on handling:**

Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.

Avoid contact with skin, eyes and clothing.

Avoid breathing vapor or mist.

Keep away from heat, sparks and flames.

Do not taste or swallow.

No smoking.

Use only with adequate ventilation.

Eliminate sources of ignition.

Avoid spark promoters.

These alone may be insufficient to remove static electricity.

Wash thoroughly after handling.

Prevent product contamination.

Keep container tightly closed and away from combustible materials.

Keep only in the original container.

Check that all equipment is properly grounded and installed to satisfy electrical classification requirements.

Container hazardous when empty.

Follow label warnings even after container is emptied.

RESIDUAL VAPORS MAY EXPLODE ON IGNITION.

DO NOT CUT, DRILL, GRIND, OR WELD ON OR NEAR THIS CONTAINER.

Improper disposal or reuse of this container may be dangerous and/or illegal.

Emptied container retains vapor and product residue.

Storage**General information on storage conditions:**

Keep container closed when not in use. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Store in upright position only. Outside or detached storage is preferred. Store in well ventilated area away from heat and sources of ignition such as flame, sparks and static electricity. Ensure that all storage and handling equipment is properly grounded and installed to satisfy electrical classification requirements. Store out of direct sunlight in a cool well-ventilated place. Store in original container. Store away from combustibles and materials to avoid. Refer also to National Fire Protection Association (NFPA) Code 400, Hazardous Materials Code. Static electricity may accumulate when transferring material. All metal and groundable storage containers, including but not limited to drums, cylinders, Returnable Intermodal Bulk Containers (RIBCs) and Class C Flexible Intermodal Bulk Containers (FIBCs) must be bonded and grounded during filling and emptying operations. Observe all federal, state and local regulations and National Fire Protection Association (NFPA) Codes which pertain to the specific local conditions of storage and use, including OSHA 29 CFR 1910.106 and NFPA 30, 70, 77, and 497.

Storage stability – Remarks:

Follow the recommended storage temperatures provided in this Section in order to maintain stability and oxygen content.

Storage incompatibility – General:

Store away from combustibles and materials to avoid.

Store separate from:

Strong acids

Strong oxidizing agents

Reducing agents

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Accelerators

Friedel - Crafts reaction catalyst

Brass

Copper

Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Temperature tolerance – Do not store above:

100 °F (38 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Engineering controls:

Investigate engineering techniques to reduce exposures below airborne exposure limits or to otherwise reduce exposures. Provide ventilation if necessary to minimize exposures or to control exposure levels to below airborne exposure limits (if applicable see above). If practical, use local mechanical exhaust ventilation at sources of air contamination such as open process equipment.

Consult ACGIH ventilation manual or NFPA Standard 91 for design of exhaust systems.

Respiratory protection:

Avoid breathing vapor or mist. Where airborne exposure is likely or airborne exposure limits are exceeded (if applicable, see above), use NIOSH approved respiratory protection equipment appropriate to the material and/or its components. Full facepiece equipment is recommended and, if used, replaces need for face shield and/or chemical goggles. Consult respirator manufacturer to determine appropriate type equipment for a given application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure or where exposure limit may be significantly exceeded, use an approved full face positive-pressure, self-contained breathing apparatus or positive-pressure airline with auxiliary self-contained air supply. Respiratory protection programs must comply with 29 CFR § 1910.134.

Skin protection:

Wear appropriate chemical resistant protective clothing and chemical resistant gloves to prevent skin contact. Consult glove manufacturer to determine appropriate type glove material for given application. Wear face shield and chemical resistant clothing such as a rubber apron when splashing may occur. Rinse immediately if skin is contaminated. Remove contaminated clothing immediately and wash before reuse. Clean protective equipment before reuse. Wash thoroughly after handling.

Eye protection:

Where eye contact may be likely, wear chemical goggles and have eye flushing equipment available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: colourless

Physical state: liquid

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Odor:	hydrocarbon-like
Odor threshold:	No data available
Flash point	84 °F (29 °C) (Setaflash closed cup)
Auto-ignition temperature:	No data available.
Lower flammable limit (LFL):	0.2 %(V)
Upper flammable limit (UFL):	> 77 %(V)
pH:	No data available
Density:	0.82 g/cm ³ (68 °F (20 °C))
Specific Gravity (Relative density):	0.824 (68 °F (20 °C))Water=1 (liquid)
Vapor pressure:	43.0 mmHg (68 °F (20 °C))
Vapor density:	No data available
Boiling point/boiling range:	Decomposes before boiling. Rate of decomposition increases with rising temperature.
Melting point/range:	No data available
Freezing point:	< -67 °F (< -55 °C)
Evaporation rate:	No data available
Solubility in water:	negligible
Refractive index:	1.4097 73 °F (23 °C)
Viscosity, dynamic:	No data available
Molecular weight:	174.3 g/mol
Oil/water partition coefficient:	No data available
Self-Accelerating Decomposition Temperature (SADT):	167 °F (75 °C) 30 pound container
Thermal decomposition:	No data available
Active oxygen content:	>= 8.81 %

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Flammability: See GHS Classification in Section 2

10. STABILITY AND REACTIVITY**Stability:**

This material is chemically unstable and should only be handled under specified conditions. See HANDLING AND STORAGE section of this SDS for specified conditions.

Hazardous reactions:

Hazardous polymerization does not occur.

Materials to avoid:

Strong acids

Strong oxidizing agents

Reducing agents

Accelerators

Friedel - Crafts reaction catalyst

Brass

Copper

Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Conditions / hazards to avoid:

See HANDLING AND STORAGE section of this SDS for specified conditions. SADT - Self Accelerating Decomposition Temperature. Lowest temperature at which the tested package size will undergo a self-accelerating decomposition reaction. This reaction will generate flammable vapors which may autoignite. The length of time to generate a decomposition reaction, after the SADT has been reached or exceeded, is dependent upon how much the SADT has been exceeded and the length of time needed for the reaction exotherm (heat spike from increasing decomposition rate) to initiate a rapid decomposition reaction. Typically, SADT is inversely proportional to package size. Larger packages will have a lower SADT due to smaller ratio to heat transfer area to volume of product.

Hazardous decomposition products:

Temperatures at or above SADT can result in the release of hazardous decomposition products which are flammable and may autoignite.

Thermal decomposition giving flammable and toxic products :

Carbon oxides

Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

Data on this material and/or its components are summarized below.

Data for LUPEROX® DTA**Acute toxicity****Dermal:**

Acute toxicity estimate > 5,000 mg/kg.

Inhalation:

4 h Acute toxicity estimate > 40 mg/l. (vapor)

LUPEROX® DTA**Data for Peroxide, bis(1,1-dimethylpropyl) (10508-09-5)****Acute toxicity****Oral:**

No deaths occurred. (rat) LD₀ > 5,000 mg/kg.

Dermal:

No deaths occurred. (rat) LD₀ > 2,000 mg/kg.

Inhalation:

No deaths occurred. (rat) 4 h LC₀ > 22 mg/l. (vapour, data for a similar material)

Skin Irritation:

Causes skin irritation. (rabbit) Irritation Index: 5/8. (4 h)

Eye Irritation:

Causes mild eye irritation. (rabbit) OECD Test Guideline 405

Skin Sensitization:

Not a sensitizer. Guinea pig maximization test. (guinea pig) Both positive and negative responses have been reported. (50 %) (Weak response, irritation was observed.)

No skin allergy was observed (10 %) (No irritation was observed.)

Repeated dose toxicity

Repeated exposure oral administration to rat / affected organ(s): kidney, liver / signs: changes in organ weights, changes in organ structure or function / No significant impairment of function. (not considered relevant to humans)

Genotoxicity**Assessment In Vitro:**

No genetic changes were observed in laboratory tests using: bacteria, human cells

Genotoxicity**Assessment In Vivo:**

Genetic changes were observed in a laboratory test using: mice

Developmental toxicity

Reproductive/Developmental Effects Screening Assay. Oral (rat) / No birth defects were observed. (similar material)

Reproductive effects

Reproductive/Developmental Effects Screening Assay. Oral (rat) / No toxicity to reproduction / (similar material)

Data for Hydroperoxide, 1,1-dimethylpropyl (3425-61-4)**Acute toxicity****Oral:**

Harmful if swallowed. (rat) LD₅₀ = 500 mg/kg.

LUPEROX® DTA**Dermal:**

Toxic in contact with skin. (rat) LD50 = 446 mg/kg.

Inhalation:

Toxic if inhaled. (rat) 4 h LC50 = 2.4 mg/l. (vapour)

Skin Irritation:

Causes severe skin burns. (rabbit) (4 h)

Eye Irritation:

Causes serious eye damage. (rabbit)

Skin Sensitization:

May cause an allergic skin reaction. Guinea pig maximization test. (guinea pig) Skin allergy was observed. (data for a similar material)

Repeated dose toxicity

Subacute inhalation administration to rat / No adverse systemic effects reported.

Genotoxicity**Assessment In Vitro:**

No genetic changes were observed in a laboratory test using: bacteria

Both positive and negative responses for genetic changes were observed in laboratory tests on similar materials using: animal cells

Reproductive effects

Reproductive/Developmental Effects Screening Assay. Oral (rat) / No toxicity to reproduction.

12. ECOLOGICAL INFORMATION**Chemical Fate and Pathway**

Data on this material and/or a similar material are summarized below.

Data for Peroxide, bis(1,1-dimethylpropyl) (10508-09-5)**Biodegradation:**

Not readily biodegradable. (56 d) biodegradation 10 % / OECD Test Guideline 301 D

Octanol Water Partition Coefficient:

log Pow = 4.73 (OECD Test Guideline 123)

Photodegradation:

Air Half-life direct photolysis: = 2.4 d

Ecotoxicology

Data on this material and/or a similar material are summarized below.

Data for Peroxide, bis(1,1-dimethylpropyl) (10508-09-5)

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Aquatic toxicity data:

No effect up to the limit of solubility. *Poecilia reticulata* 96 h LC0 > 170 mg/l (similar material)

Aquatic Invertebrates:

May be harmful. *Daphnia magna* (Water flea) 48 h EC0 > 73.1 mg/l (similar material)

Algae:

No effect up to the limit of solubility. *Pseudokirchneriella subcapitata* (green algae) 72 h EC50 > 200 mg/l (Nominal concentration)

Microorganisms:

No effect up to the limit of solubility. Respiration Inhibition / Activated sludge 30 min EC50 > 160 mg/l (similar material)

13. DISPOSAL CONSIDERATIONS

Waste disposal:

Dilution followed by incineration is the preferred method. Dilution ratio of 10:1 in a clean, compatible, combustible solvent (i.e., Fuel Oil #2, mineral oil) will reduce reactivity hazard during incineration and transportation. Dispose of in accordance with federal, state and local regulations. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits. Note: Chemical additions to, processing of, or otherwise altering this material may make this waste management information incomplete, inaccurate, or otherwise inappropriate. Furthermore, state and local waste disposal requirements may be more restrictive or otherwise different from federal laws and regulations.

Take appropriate measures to prevent release to the environment.

14. TRANSPORT INFORMATION

US Department of Transportation (DOT)

UN Number : 3107
 Proper shipping name : Organic peroxide type E, liquid
 Technical name : (Di-tert-amyl peroxide, <=100%)
 Class : 5.2
 Marine pollutant : no

International Maritime Dangerous Goods Code (IMDG)

UN Number : 3107
 Proper shipping name : ORGANIC PEROXIDE TYPE E, LIQUID
 Technical name : (DI-tert-AMYL PEROXIDE, <=100%)
 Class : 5.2
 Marine pollutant : no
 Flash point : 84 °F (29 °C) Setflash closed cup

15. REGULATORY INFORMATION

LUPEROX® DTA

Chemical Inventory Status

EU. EINECS	EINECS	Conforms to
United States TSCA Inventory	TSCA	The components of this product are all on the TSCA Inventory.
Canadian Domestic Substances List (DSL)	DSL	This product contains one or several components listed in the Canadian NDSL list. All other components are on the DSL list.
China. Inventory of Existing Chemical Substances in China (IECSC)	IECSC (CN)	Conforms to
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Conforms to
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Conforms to
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Conforms to
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	Does not conform
Australia Inventory of Chemical Substances (AICS)	AICS	Conforms to

United States – Federal Regulations

SARA Title III – Section 302 Extremely Hazardous Chemicals:

The components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.

SARA Title III - Section 311/312 Hazard Categories:

Acute Health Hazard, Fire Hazard, Reactivity Hazard, Chronic Health Hazard

SARA Title III – Section 313 Toxic Chemicals:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):

Chemical name	CAS-No.	Reportable quantity
2-Butanol, 2-methyl-	75-85-4	100 lbs

United States – State Regulations

Product code: 762000

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LUPEROX® DTA**New Jersey Right to Know**

No components are subject to the New Jersey Right to Know Act.

Pennsylvania Right to KnowChemical name

Peroxide, bis(1,1-dimethylpropyl)

CAS-No.

10508-09-5

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive defects.

16. OTHER INFORMATION**Full text of H-Statements referred to under sections 2 and 3.**

H226	Flammable liquid and vapour.
H242	Heating may cause a fire.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H411	Toxic to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

Miscellaneous:

Other Information: Refer to National Fire Protection Association (NFPA) Codes 30, 70, 77, and 497 and OSHA 29 CFR 1910.106, for safe handling.

Latest Revision(s):

Reference number: 200014307
Date of Revision: 02/07/2017
Date Printed: 02/07/2017

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The statements, technical information and recommendations contained herein are believed to be accurate as of the date hereof. Since the conditions and methods of use of the product and of the information referred to herein are beyond our control, ARKEMA expressly disclaims any and all liability as to any results obtained or arising from any use of the product or reliance on such information; **NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE GOODS DESCRIBED OR THE INFORMATION PROVIDED HEREIN.** The information provided herein relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. The user should thoroughly test any application before commercialization. Nothing contained herein constitutes a license to practice under any patent and it should not be construed as an inducement to infringe any patent and the user is advised to take appropriate steps to be sure that any proposed use of the product will not result in patent infringement. See SDS for Health & Safety Considerations.

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Arkema has implemented a Medical Policy regarding the use of Arkema products in Medical Devices applications that are in contact with the body or circulating bodily fluids (<http://www.arkema.com/en/social-responsibility/responsible-product-management/medical-device-policy/index.html>) Arkema has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by Arkema for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, Arkema strictly prohibits the use of any Arkema products in Medical Device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. The Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices, and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices.

It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade Arkema products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements (FDA or other national drug agencies) It is the sole responsibility of the manufacturer of the medical device to conduct all necessary tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance obligations. Any decision regarding the appropriateness of a particular Arkema material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.

